NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute For Regenerative Medicine
Chapter 4

Date: April 4, 2008

Deadline for Submission of Written Comment: May 19, 2008 – 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Amendments: Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations

Sections Affected:

The proposed regulations amend Chapter 4 of Title 17 of the California Code of Regulations, sections 100407 and 100408.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Sections 125290.30, 125290.40, 125290.55, 125300, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens' Oversight Committee ("ICOC") is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations

focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

Historically, the involvement of the for-profit research sector has been essential for the discovery and development of medical therapies and diagnostics. The California Stem Cell Research and Cures Act provides for the funding of for-profit research organizations (companies) in California to advance the development of products for public use. The current regulations, sections 100400 – 100410, compose the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations, approved by the Office of Administrative Law in March of 2008, and provide terms and conditions to for-profit recipients of CIRM funds.

The proposed amendments apply to section 100407, Access Requirements for Products Developed by For-Profit Grantees, and section 100408, Revenue Sharing. Section 100407 provides the terms applicable to grantees and their exclusive licensees when a Drug is commercialized in California. This regulation requires a Grantee or its Exclusive Licensee to submit an access plan to CIRM, describes the plan's elements, and requires provision of the Drug to certain purchasers at certain benchmark prices identified in the California Discount Prescription Drug Program ("CDPDP") (or its successor program). Based on comments received at the time the current regulation was approved by the ICOC in December of 2007, the ICOC approved the proposed amendments to initiate the process of receiving public comment on them. The proposed amendments clarify the timing of the submission of a proposed access plan to the CIRM, state the plan will be subject to the approval of CIRM after a public hearing, and clarify the application of CDPDP benchmarks in the event the program is repealed.

Section 100408 describes the revenue sharing requirements for Grantees. Subdivision (b) of the existing regulation describes revenue sharing when the Grantee self-commercializes a product (as opposed to licensing an invention, covered by subdivision (a)). The regulation is intended to apply a tiered approach to payback to the state based on revenue triggers. As stated in the introductory language of subdivision (b), the royalty payments in the subsections that follow it are payable regardless of whether a CIRM-funded Patented Invention is involved. In subdivision (b)(2), the payments described are triggered when the described milestones are reached from a self-commercialized CIRM-funded Patented Invention. Because that language may appear to contradict the language in subdivision (b), which applies the triggers regardless of a CIRM-funded Patented

Invention, the proposed amendments clarify the intent of the regulation by referring to products resulting from "CIRM-funded Research."

Technical, Theoretical or Empirical Studies, Reports or Documents:

None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on May 19, 2008. Comments regarding this proposed action may also be transmitted via e-mail to forprofitipregs@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than May 5, 2008.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulations implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory actions.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed actions will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; inquiries regarding the rulemaking file; and questions on the substance of the proposed regulatory action may be directed to:

C. Scott Tocher, Counsel to the Vice-Chair
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

These questions may also be addressed to:

Pat Becker, Senior Executive Assistant
California Institute for Regenerative Medicine
(415) 396-9100

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above.